

We claim:

1. A removable aerosolizing element for use in an aerosol delivery device for aerosolizing an agent, comprising:
  - 5 a body having an exterior surface and a chamber defined therein;
  - an inlet defined in the body for connection to a source of agent, the inlet being in fluidic communication with the chamber;
  - agent releasing orifices defined in the body and in communication with the chamber; and
- 10 a movable element having an inner surface that defines a portion of the chamber, the movable element being capable of moving in response to an external force applied to the outer surface to expel agent in the chamber through the orifices.
2. The aerosolizing element of claim 1, wherein the movable portion is deformable, and the movable portion deforms under the external force to increase pressure in the chamber, thereby expelling agent from the chamber through the orifices.
3. The aerosolizing element of claim 1, wherein the movable element comprises a flexible diaphragm.
- 20 4. The aerosolizing element of claim 1, wherein the chamber includes an internal passageway portion in communication with the inlet and a main chamber portion generally opposite the orifices.
- 25 5. The aerosolizing element of claim 1, wherein the chamber is filled with a predetermined quantity of agent and the inlet is sealed.
- 30 6. The aerosolizing element of claim 1, further comprising a removable cover positioned over the inlet to reduce entry of undesired material into the chamber, the cover being removable for connecting the element to the source for filling with agent.
7. The aerosolizing element of claim 1, wherein the body comprises an orifice plate partially bounding the chamber generally opposite the movable element, the orifice plate defining the orifices.

8. The aerosolizing agent of claim 7, wherein the orifice plate comprises a metal foil.

9. The aerosolizing element of claim 1, wherein the chamber can be filled with 5 agent via gravity feed from the inlet.

10. The aerosolizing element of claim 1, wherein the chamber can be filled with agent via capillary action.

11. The aerosolizing element of claim 1, further comprising projections disposed in the chamber and maintaining a minimum spacing between the movable element and the orifices.

12. The aerosolizing element of claim 1, wherein the external force applied to 15 the movable member comprises vibratory oscillations causing the movable member to reciprocate and alternately increase pressure in the chamber to expel agent and decrease pressure to draw additional agent into the chamber.

13. The aerosolizing element of claim 1, wherein the element is pre-filled with 20 at least a first component and a second component of an agent to be aerosolized that are mixed within the element prior to aerosolization.

14. The aerosolizing element of claim 13, wherein body comprises a first reservoir pre-filled with the first component of the agent, a second reservoir pre-filled with 25 the second component of the agent, and a separation element disposed between the first and second reservoirs and separating the first component from the second component, the separation element being movable into the first reservoir to allow mixing of the first and second components.

15. The aerosolizing element of claim 1, wherein the body includes a needle portion shaped to receive a vial of agent and wherein an end of the needle defines the inlet.

16. The aerosolizing element of claim 1, wherein the element is disposable after use.

17. The aerosolizing element of claim 1, wherein one side of the body is adapted for direct attachment to a patient interface for conveying aerosolized agent from the orifices towards a patient.

5 18. The aerosolizing element of claim 1, wherein the chamber includes an air vent separate from the inlet.

10 19. The aerosolizing element of claim 1, wherein:  
the aerosol delivery device comprises an actuator that applies the external force to  
the movable element to cause the agent to be expelled through the orifices; and  
the body is configured to prevent the agent from contacting the actuator.

15 20. The aerosolizing element of claim 1, further comprising at least one airflow passageway extending through the body such that air flowing through the passageway can carry the expelled agent away from the element.

20 21. The aerosolizing element of claim 20, wherein the airflow passageway comprises an inlet defined in one side of the body and an outlet defined in an opposing side of the body, the outlet being offset from the inlet.

25 22. The aerosolizing element of claim 1, wherein the body comprises first and second reflective surfaces positioned on opposite sides of the orifices such that a light beam passing through the element is reflected by the first reflective surface to extend in front of the orifices and onto the second reflective surface, which reflects the light beam back through the element.

23. The aerosolizing element of claim 22, wherein the body comprises a transparent material that transmits the light beam.

30 24. The aerosolizing element of claim 3, wherein the flexible diaphragm comprises a plurality of projections that maintain a minimum chamber thickness.

35 25. The aerosolizing element of claim 3, wherein the body comprises an opening adjacent the flexible diaphragm, the opening being adapted to receive an actuator for coupling to the flexible diaphragm and applying the external force.

26. An aerosolizing device, comprising:  
a housing sized and shaped to be held in a hand of a user;  
a disposable aerosolizing element disposed in the housing and capable of expelling  
5 aerosolized agent;  
an oscillator disposed in the housing and positioned to exert vibratory oscillations  
on a portion of the disposable aerosolizing element to aerosolize agent in the element; and  
a patient interface coupled to the housing and shaped to deliver aerosolized agent  
expelled from the disposable aerosolizing element to a patient,  
10 wherein the disposable aerosolizing element is removable from the housing for  
installation and disposal.

27. The device of claim 26, further comprising a compressed air source  
configured to supply compressed air to the device to assist in delivery of aerosolized agent  
15 through the patient interface.

28. The device of claim 27, wherein some of the air conveyed by the  
compressed air source is directed to cool the oscillator.

20 29. The device of claim 26, further comprising air inlet holes positioned to  
allow entry of atmospheric air into the device to assist in delivery of aerosolized agent  
through the patient interface.

25 30. The device of claim 26, wherein the disposable aerosolizing element has an  
internal chamber at least partially defined by a flexible portion that can be manually  
squeezed by a user to create a negative pressure within the chamber to assist in filling the  
chamber with agent.

31. The device of claim 26, wherein the disposable aerosolizing element has an  
inlet for receiving an agent to be aerosolized and prevents the agent from contacting the  
oscillator.  
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32. The device of claim 26, further comprising:  
a body-mountable pack that is worn or carried on the user's body; and

a power source for the device comprising one or more batteries disposed in the pack.

33. The device of claim 32, further comprising an air pump disposed in the  
5 pack and an air conduit fluidly connecting the air pump to the housing, the air pump being  
operable to supply compressed air to the housing to assist in delivery of aerosolized agent  
through the patient interface.

34. The device of claim 32, wherein the pack is worn around the user's waist or  
10 on the user's shoulder.

35. The device of claim 26, wherein the patient interface comprises a  
disposable mask shaped to fit around the mouth and nose of the patient.

15 36. The device of claim 35, wherein the mask comprises a material that is  
porous to air.

37. The device of claim 26, wherein the patient interface comprises a one-way  
valve that is operable to permit flow from the disposable aerosolizing element to the patient  
20 through the patient interface, and to inhibit flow in the reverse direction through the patient  
interface.

38. The device of claim 37, wherein the one-way valve comprises a duckbill  
valve.

25 39. The device of claim 26, wherein the patient interface comprises one or more  
baffles that shield the disposable aerosolizing element from expired particles.

40. The device of claim 26, further comprising an aerosolization rate monitor  
30 that is operable to detect the rate at which agent is aerosolized by the aerosolizing element.

41. The device of claim 26, further comprising a counting device that is  
operable to record the number of doses that are administered by the device.

42. A handheld aerosolizing device, comprising:  
a disposable aerosolizing element capable of expelling aerosolized agent;  
a battery-powered actuator positioned to exert vibratory oscillations on a portion of  
the disposable aerosolizing element to aerosolize agent in the element; and  
5 a patient interface shaped to deliver aerosolized agent expelled from the disposable  
aerosolizing element to a patient,  
wherein the aerosolizing element prevents the agent from contacting the actuator.

43. The device of claim 42, wherein a fluid passageway from a source of agent  
10 to the patient interface is substantially contained within the aerosolizing element and the  
element is separately removable from the device.

44. The device of claim 43, wherein the source of agent is contained within the  
aerosolizing element.

15 45. The device of claim 43, wherein the aerosolizing element is shaped for  
direct connection to the source of agent.

46. The device of claim 42, wherein the aerosolizing element is pre-filled with  
20 a volume of agent and sealed against leakage prior to use.

47. The device of claim 46, wherein the volume of agent is sufficient for  
delivery of multiple single doses.

25 48. The device of claim 47, further comprising a vial containing agent for direct  
coupling to the aerosolizing element.

49. The device of claim 42, wherein the patient interface comprises a mask  
intended for disposal after each use.

30 50. The device of claim 42, wherein the patient interface comprises a mask  
intended for disposal after each use that is porous and entraps expired aerosols from the  
patient.

51. The device of claim 42, wherein the patient interface is a nasal prong intended for disposal after each use.

52. The device of claim 42, further comprising an aerosolization rate monitor  
5 that allows monitoring of aerosolizing rates during use.

53. The device of claim 52, wherein the aerosolization rate monitor comprises a light source operable to project a light beam that extends through aerosol droplets being expelled by the aerosolizing element and a light detector operable to detect the obscuration  
10 of the light beam caused by the aerosol droplets.

54. The device of claim 53, wherein the aerosolization rate monitor comprises a controller and a visual indicator, wherein the controller receives the signal from the light detector and determines an aerosolization rate based on the signal, and the visual indicator  
15 provides a visual indication regarding the aerosolization rate.

55. The device of claim 53, wherein the aerosolizing element comprises first and second reflective surfaces, the first reflective surface being positioned to reflect the light beam from the light source to extend in a first direction through the aerosol droplets, the  
20 second reflective surface being positioned to reflect the light beam extending through the aerosol droplets to extend in a second direction toward the light detector.

56. The device of claim 42, wherein at least the aerosolizing element and the oscillator are arranged together in a housing sized for holding in a hand of user.

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57. The device of claim 42, further comprising a component separate from the housing in which at least batteries are positioned, the component having a power connection to the housing and adapted to be worn or carried on a user's body.

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58. A method of using an aerosolizing device, the method comprising administering an aerosolized agent from the aerosolizing device by applying vibratory oscillations to a disposable aerosolizing element in the aerosolizing device and disposing of the aerosolizing element after administering the agent.